K992702

NOV - 8 1999

## FDA 510(K) Summary

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| Submitter: | Allergydirect.com<br>8800 East 63rd Street<br>Kansas City<br>Missouri, 64133<br><br>Tel: 816 356 0200<br>Fax: 816 246 9592 |
| Contact: | Gavin McLachlan - Ext. 542<br>Director |
| Date Prepared: | November 3, 1999. |
| Device Names: | eVENT™ Allergen Barriers<br>eVENT™ Mattress encasing<br>eVENT™ Duvet encasing<br>eVENT™ Pillow Encasing<br>eVENT™ Bedding System |
| Common Name: | Mattress/Bedding Material Covers |
| Classification Name: | Mattress Cover for Medical Purposes |
| Comparable Products: | Allergy Control™ Products<br>ACb™ Elite<br>ACb™ Sheer |
| Product Description: | eVENT™ Allergen Barriers consist of mattress, pillow and duvet/comforter encasings. The products consist of an expanded PTFE membrane laminated to a synthetic or synthetic/natural combination fabric. The expanded PTFE membrane provides a moisture-vapor & air permeable ("breathable") barrier with pores too small to allow passage to either house dust mites or their allergen containing fecal droppings. The fabric component provides a strong, easily maintained support for the ePTFE membrane. eVENT™ Allergen Barriers are soft, comfortable and easy to clean; They are simply damp-dusted when the bed sheets are changed.<br><br>Allergydirect.com's membrane manufacturing process is sufficiently controlled to ensure uniform nominal pore sizes too small to permit the passage of either the house dust mites or their droppings. eVENT™ |

Allergen Barriers provide high levels of protection from house dust mite allergens. The membrane's vapor permeable characteristics help promote sleeping comfort. Thus, eVENT™ Allergen Barriers serve as an effective barrier between a patient and a cause of their allergies; this results in a healthier, more comfortable sleeping environment.

Intended Use:

Expanded PTFE products are widely used as fabrics for outdoor wear; as industrial filtration devices; in electrical components; as implantable medical devices; and as non-implanted health care products such as cast liners. PTFE is an inert, biocompatible polymer, the safety of which is well documented in medical and scientific literature.

Asthma, eczema and allergic rhinitis are chronic conditions or diseases that are frequently managed to some extent by allergen avoidance techniques. Recent medical literature reports that the frequency and/or severity of these diseases are often associated with patient allergy to the fecal droppings of house dust mites. House dust mites are found in high concentrations in bedding materials. eVENT™ Allergen Barriers have been designed exclusively for allergy sufferers wishing to reduce their exposure to house dust mite allergens in mattresses, pillows and duvet/comforters.

Product Performance:

The combination of the ePTFE membrane and the fabric substrate result in bedding covers which are more comfortable than the vinyl or other plastic bedding covers currently available. Test data demonstrating that eVENT™ Allergen Barriers are over 2 times (Modified Desiccant Method [MDM] dry method) more "breathable" than the comparable Allergy Control Products' ACb® Elite and over 4 times more "breathable" than Allergy Control Products' ACb® Sheer are included. eVENT™ Allergen Barriers are easily maintained, requiring only damp dusting when the bed sheets are changed.

## STATEMENT OF SUBSTANTIAL EQUIVALENCE TO THE PREDICATE DEVICES

The use of barrier products is well established as a means of allergen avoidance. eVENT™ Allergen Barriers provide an appropriate barrier to house dust mites and their allergenic fecal matter, while providing a very comfortable sleeping surface. eVENT™ Allergen Barriers are substantially equivalent to the currently marketed predicate devices produced by Allergy Control Products, Inc.

Both the predicate and applicant devices are intended for use as allergen barriers on bedding materials. The products are substantially equivalent in terms of material and construction. The use, care of, and handling of eVENT™ Allergen Barriers is similar to that of the predicate barrier products, and will present little difference for users. Laboratory tests demonstrate eVENT™ Allergen Barriers' ability to serve as a barrier to house dust mites and their fecal matter. Additional testing demonstrates eVENT™ Allergen Barrier's strength, softness and ease of cleaning.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Gavin McLachlan
Director
Allergy Direct™
8800 East 63rd Street
Kansas City, MO 64133

Re: K992702
Trade Name: eVENT™ Allergen Barriers
Regulatory Class: I
Product Code: FMW
Dated: July 29, 1999
Received: August 12, 1999

Dear Mr. McLachlan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992702

Device Name: eVENT™ Allergen Barriers

Indications For Use:

Designed exclusively for allergy suffers wishing to reduce their exposure to house dust mite allergens in mattresses, pillows and duvet/comforters.

Encase the mattress, pillow and duvet/comforter in eVENT™ Allergen Barriers, then install your regular bed linens over the allergen barrier enclosings.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cucuzza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992702